EXHIBIT B

RULE 26 GENERAL LIABILITY AND CAUSATION REPORT BY KEITH O. REEVES, M. D. ON C.R. BARD ALYTE PRODUCT

I am Dr. Keith O. Reeves. The medical opinions rendered in this report represent my opinions, all held to a reasonable degree of medical certainty, and are based on a reasonable medical probability and scientifically reliable evidence.

I. BACKGROUND AND QUALIFICATIONS

I am currently an Emeritus Physician at the Houston Methodist Hospital, Department of Obstetrics and Gynecology. I am also the Founding Medical Director for the Methodist Center for Restorative Pelvic Medicine. I have served as Professor of Clinical Obstetrics and Gynecology for Weill Medical College of Cornell University and Clinical Associate Professor for the Baylor College of Medicine. I received my MD degree in 1970 from the Baylor College of Medicine and completed my residency in obstetrics and gynecology at the same institution in 1976. I have taught vaginal surgery to resident physicians since 1976. In 2006, I became the Founding Medical Director of the Methodist Hospital Center for Restorative Pelvic Medicine, and created a multi-specialty entity consisting of urologists, gynecologists, colorectal surgeons, plastic surgeons, and pelvic floor physical therapists to cater specifically for the needs of patients with complex pelvic floor problems beyond the scope of many community physicians. In the years since its creation, the center has flourished, and patients come from around the country and the world to receive treatment. Several years ago, we created a fellowship-training program, and gynecologists and urologists who have completed residency training now spend an additional three years with us to obtain advanced training in voiding dysfunction, reconstructive pelvic surgery, and female pelvic medicine. Within the last three years, this program has become only the third fellowship program in the state of Texas to be accredited by the ACGME and approved by the American College of Obstetricians and Gynecologists.

OPINIONS REGARDING BARD PRACTICES AND PRODUCTS

Bard's ALYTE mesh is not suitable for its intended application as a permanent prosthetic implant for POP and general liability in the human body and is defective and unreasonably dangerous because the manufacturer of its raw polypropylene resin has clearly warned that it should not be placed inside the human body.

Bard’s Alyte product and other pelvic mesh products, as well as several of Bard’s hernia mesh products are constructed from a polypropylene resin manufactured by the Phillips Sumika Corporation. Federal regulations require that raw materials such as polypropylene resin all be accompanied and identified by what is known as a “Material Safety Data Sheet” or MSDS. The purpose of the MSDS is to warn of any potentially hazardous materials in such raw materials.

Bard executive Roger Darois testified in the Cission trial that the material manufacturer, Phillips Sumika, is required to produce a MSDS to the "customers that buy the resin." Polypropylene resin used in Bard's pelvic mesh products is Marlex HGX-030-01, manufactured by Phillips Sumika (formerly a subsidiary of Chevron Phillips). Bard received from Phillips Sumika a material safety data sheet for its Marlex polypropylene resin used in the Alyte mesh. As explained in more detail below, a company called Red Oak was Bard's exclusive supplier of the extruded HGX-30-01 material, having purchased the HGX- 030-0 I resin from Phillips Sumika and extruded the resin into monofilament. Specifically, as Mr. Darois testified, Phillips Sumika was required to produce the Marlex MSDS to Red Oak. *Id.* The MSDS for the Phillips Sumika Marlex HGX-030-01 resin expressly prohibits use of the material for permanent human implantation, stating:

MEDICAL APPLICATION CAUTION: ***Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.***[46]

Bard went to great efforts to hide from Phillips Sumika the fact that it was using its polypropylene material for the expressly prohibited purpose of permanent human implantation. Bard executive Roger Darois testified during the *Cission* trial that Bard did not want Phillips Sumika to know that Bard was using its material for permanent implantation.[47] In fact, Darois admitted in his *Cission* trial testimony that Bard made efforts to conceal its use of the material from Phillips Sumika and others because Bard knew that Phillips Sumika would not allow it to continue using its material for permanent implants if it found out.[48]

In order to obtain the material from Phillips Sumika without its knowledge, Bard employed a scheme of using straw men to obtain the resin. Since 1998, Red Oak has been the intermediary that Bard has used to purchase the material from Phillips Sumika. *(Id.*, 76:23-77:10). The importance to Bard's scheme of acquisition of polypropylene resin through an intermediary is illustrated in a series of internal Bard documents. In 2004, when an employee of a German Bard subsidiary inquired about a source for polypropylene for a research project, Roger Darois warns that the resin manufacturer (Phillips Sumika) does not realize its material is being used in humans, and that it is "important" to use an intermediary to purchase the resin in order to prevent the manufacturer from discovering that they are using it for implant purposes, stating:

> IMPORTANT ...these suppliers will likely not be interested in a medical application due *to product liability concerns. We purchase our polypropylene monofilament from an extrusion supplier who purchases the resin directly from the resin manufacturers. Thus, it is likely that they do not know of our implant application. Please do NOT mention Davol's name in any discussions with these manufacturers. In fact, I would advise purchasing the resin through a 3rd party, not the resin supplier to avoid a supply issue once the medical application is discovered* .[49]

That same day, Davol Senior Engineer Bill Grennan explained in an e-mail: *"We supply the extrusion equipment and our vendor purchases the resins and extrudes the monofilament*

for us" and reiterated that it should not be revealed to the resin manufacturer that Bard was using its polypropylene for permanent implantation, stating:

> *Once again, we need to be certain that we don't contact the resin supplier directly due to the sensitivity of our implant application.*[50]

The German Bard employee got the message, responding: *"I can assure you that I understand the sensitivity of the supplier issue and therefore won't contact the supplier directly."*[51]

This conspiracy to prevent Phillips Sumika from learning that its polypropylene was being used for implantation - in part by using Red Oak to purchase the material - continued for years. By way of background, Shakespeare Monofilaments (affiliated with the Shakespeare Company, which manufactures fishing tackle) contracted with Bard to perform part of the processing of the polypropylene used in certain of Bard's mesh devices.[52] While Bard's documents reflect that Shakespeare was aware that the material it was processing for Bard was intended for medical implantation, it is clear that Shakespeare was never informed that the resin used was specifically contraindicated for such applications. In 2007, Shakespeare discovered the Phillips Sumika Marlex MSDS, and thereafter refused to have any part in the scheme[53]

When Shakespeare advised Bard that it would not process any more of this material, Bard attempted to convince Shakespeare to look the other way by offering it indemnity. This offer was approved by Bard's Associate General Counsel, Jack Myers. Davol's Jim Brann stated in his e-mail: *"I had received an OK from Jack Myers that Bard would indemnify Shakespeare"*[54] Shakespeare again refused to process the material for Bard. As Brann's e-mail states, *"Shakespeare responded that under no circumstances, even with* [Bard's] *indemnification... will they produce another lot."*[55]

Shakespeare's refusal to process the mesh left Bard with a supply chain issue. Bard's solution to this supply problem was to use another company, Secant Medical, to perform part of the processing that had been performed by Shakespeare[56] However, Bard was concerned that Secant might discover - as Shakespeare had - that this material was not intended for permanent implantation in humans, and Bard made it clear that this was a fact that must be concealed from Secant. What the correspondence also made clear is that Bard was equally concerned about Secant discovering its relationship with Red Oak, which Darois described as "vertical integration" and calling Red Oak "captive with Davol assets."

Darois cautioned that *"Secant know[s] that we are 'vertically integrated' with respect to PP monofilament extrusion but DOES NOT KNOW that Red Oak is our extrusion supplier (captive with Davol owned assets) or that Red Oak purchases the Phillips Marlex resin without Phillips knowledge for its use in a medical device. We need to keep this proprietary"*[57] (emphasis added). Bard set in motion a scheme to prevent Secant from discovering its prohibited use of this material, including a scheme to prevent it from learning about its "vertical integration" with Red Oak that went so far as to remove Red Oak's name from items, with Darois stating: *"[W]e need to ensure that none of the Red Oak name labeling on spools, sipping [sic] containers, packing slips, etc. makes it to Secant to maintain our confidential extrusion source until we make a conscious decision to share this with them." Id.* According to Bard's internal documents, Red

Oak was integrally involved in the subterfuge employed by Bard to hide this information from the supplier - and from everyone in its processing chain.

In my considered medical opinion, I cannot envision any physician who took the Hippocratic Oath at the time of medical school graduation knowingly using a product as part of a surgical procedure that has expressly been forbidden for use inside the human body by the product manufacturer. Bard's extraordinary subterfuge in its endeavor to hide the intended use of polypropylene from the product supplier is deceitful and far outside the boundaries of corporate ethics. How can they be trusted or believed regarding anything they produce?

There is literature showing reports of cancer associated with polypropylene. Specifically, there have been cases of pseudotumor reported in polypropylene for hernia mesh[58] and inflammatory myofibroplastic tumor of low malignant potential with a TVT device.[59] In addition, there have been 2 cases of bowel cancer associated with mesh used for abdominal sacrocolpopexy, one associated with Mersilene and one with polypropylene and TVT placement.[60] A case of primary vaginal leiomyosarcoma associated with TVT and anterior repair with Bard Duraderm has also been reported. Finally, a report of angiosarcoma associated with Darcon vascular grafts was reported in 1999.[61] The authors of this article noted at least (8) other sarcomas developing at the site of vascular prosthesis, and that the rate of these sarcomas, associated with foreign bodies, was much higher than the rate of sarcomas in general. All sarcomas associated with Dacron grafts were high grade histology and disseminated at the time of presentation. The authors also describe sarcomas reported at the site of other foreign bodies, such as shrapnel, bullets, steel plates and retained surgical sponges. They also note that the latency period from the acquisition of the foreign body and the development of sarcoma had a mean of (33) years. They postulate that a chronic foreign body reaction was the etiology of this carcinogenesis. The authors also describe sarcomas developing in rodents after inert plastic polymers were placed in their soft tissue: "The sarcomas developed in rodents in which thick fibrous capsules developed around the implanted material." The authors conclude: "For unknown reasons, the cells in this inflammatory and repair process may undergo a malignant transformation, probably associated with oncogene activation and tumor suppressor gene inactivation. Further studies are warranted to search for the mechanisms involved in foreign body oncogenic potential.

The Bard Alyte product was cleared for use via the 510(k) process on November 10, 2009. The predicate devices were Mpathy Medical Devices Ltd. "Minimesh" K053361 and American Medical Systems' Y-Mesh Graft K033636, K040521.[62] As such, Bard was not required to submit any clinical trials demonstrating the safety or efficacy of its device. The product was removed from the market December 31, 2016, following the FDA Bulletin of April 16, 2019 demanding that all mesh products be taken off the market. Previously, on January 5, 2016, the FDA had reclassified surgical mesh for transvaginal repair of pelvic organ prolapse as a class III device, necessitating the agency's most stringent review.[63]

The Alyte device is a "Y" shaped piece of polypropylene that is single thickness for the pieces attaching to the anterior and posterior serosal walls of the vagina but is double thickness where these two single layers meet for attachment to the sacrum. This double thickness affects the porosity and pore size of the sacral attachment piece and the anterior and posterior vaginal arms.

"The geometry and dimensions of the mesh pores have been found to impact the biologic response to mesh directly. Indeed, greater pore sizes were found to yield mesh-tissue composites of greater strength and increased collagen deposition; smaller pores restricted vascular growth and contains less mature collagen. Notably, it has been shown that effective tissue in-growth, which is characterized by the quality of the tissue that forms between mesh fibers, occurs in mesh pores with a diameter of $\geq$1 mm for polypropylene mesh."[64] Barone and his colleagues further note that, "Importantly, pore diameters of <1 mm are associated with an enhanced inflammatory response that accompany poor tissue in-growth and fibrotic encapsulation. Thus, it is not surprising that nearly all contemporary vaginal mesh products are constructed with initial pore diameters of >1 mm. Yet, despite this design feature, it is not uncommon for mesh to appear bunched after implantation, particularly in areas of complications."[64] In this study Barone designed a device to place vaginal meshes under stress along only one axis, and he then stretched the meshes with defined amounts of force, designated as "N" (Newton). Force is equal to one N if it accelerates a mass of one 1 kilogram to 1 m/s^2. After applying different amounts of force to four separate meshes, (Gynemesh, Alyte, UltraPro and Restorelle) he checked the porosity of the mesh following force application. After applying a force of 5N, Alyte had the greatest decrease in porosity, by 14.5%. "At 10N of force, all mesh groups other than Restorelle experienced such large pore reductions that the mesh structure grossly appeared as a solid piece of polypropylene.[64] "However, a major finding of this study that was not anticipated was that the porosity of nearly all tested products approached 0% in response to just 10N of applied force, which is within the expected physiologic range consistent with the forces we would expect to experience before tissue incorporation (during implantation and in vivo). Additionally, this study found that the pore diameters of synthetic mesh are extremely sensitive to uniaxial forces. By 10N nearly all meshes that were tested had zero pores with a diameter of <1mm."[64] Finally, fibrous encapsulation and its potential contraction by resident myofibroblasts may induce pain after mesh implantation, which is one of the most common of mesh related complications.[64]

There is no definitive knowledge about what harmful side effects these products can cause after years in the human body. Many women have polypropylene mesh implanted prior to the onset of menopause, and with the decreased estrogen tissue levels typical of menopause, the vaginal mucosa thins and atrophies, increasing the potential for mesh erosion with increasing patient age. These products are not unlike land mines used in warfare and abandoned at the end of armed conflict, which remain hidden but deadly for years to come. Fortunately, land mines can be removed. Unfortunately, the supporting arms of vaginal mesh go so far into the hinterland of the pelvis that it is extremely difficult if not impossible to remove all of it in subsequent surgical procedures. It remains in place, with unknown potential for pain, scarring, inflammation and degradation.

The Alyte mesh product is not suitable for its intended application as a permanent prosthetic implant sewn onto the anterior and posterior vaginal walls, and its double thickness anchor sewn into the sacral promontory due to its frequent tendency to "curl", also known as "cording" and/or "roping", as well as fraying during and after placement in the body, thus making its design defective and unreasonably dangerous.

Bard's Alyte mesh is ostensibly designed to lie flat after having been sewn onto the serosa of the anterior and posterior vaginal walls and the sacral promontory. However, once sewn into

position, it does not necessarily lie flat. As has been described above in the Barone study, forces typically present in the female pelvis are easily sufficient to alter pore size and cause a previously flat piece of mesh to become "cord like", impeding tissue ingrowth, and causing an increased inflammatory response and the pain associated with this. The cording phenomenon can also result in frayed and sharp edges on the sides of the mesh. As this occurs, the patient may suffer from mesh erosion and pain, and her sexual partner is at risk of penile laceration due to the eroded mesh penetrating the vaginal mucosa and causing injury to him during coitus. Cording and curling was recognized by Bard as a problem that it wanted to avoid as far back as 2006 when the Align device (an Alyte polypropylene predecessor) was being developed. In a September 19, 2006 PowerPoint presentation entitled" Update on Sling Integration Project" a slide entitled "Mesh Design" stated that the mesh design of Align "improves recovery to prevent cording" and that "when used in cadaver labs, mesh has laid very flat under the urethra".[49] In another PowerPoint, it was stated that," We designed the new mesh with optimal integrity for optimal functionality under the urethra in particular the stability of the mesh was improved to prevent cording and fraying during insertion of the mesh."[65] A Bard employee named Walter Freitag, who was a member of the engineering team for the development of Align, agreed in his deposition that one of the purposes of creating Align was to attempt to prevent cording and fraying during the insertion of the mesh.[66] In fact, Bard knew as early as 2001 that polypropylene slings created a "high risk of erosion and infection."[66] Women like Ms. Hinnewinkel clearly demonstrate that Bard has not made much progress since 2006 in preventing cording of its mesh products.

Another Bard employee, Ronald Bracken was vice president of research and development for the Bard medical division between 2006 and 2011.[67] He was responsible for overseeing the development of all Bard pelvic organ prolapse meshes and slings between June 2009 and October 2011.[68] Mr. Bracken admitted in his testimony that a mesh's inability to integrate well into the tissue and undergo tissue remodeling around it can result in adverse events such as vaginal erosions, urethral erosions, bladder erosions, and chronic pain.[69] He additionally testified it was the responsibility of Bard engineers who developed Align to "design out or minimize as much risk as possible."[70] The Bard engineers developing vaginal mesh products knew that cording was a serious risk to the patient and resulted in "potential effects of failure quote caused by cording or twisting."[71] Walter Freitag testified in his deposition that cording of Bard meshes would "increase your potential occurrence for erosion to the extent something like that happens."[72]

When a polypropylene mesh curls or cords, it can also result "in fraying of the mesh" and "shedding of polypropylene particles". Both of these failure modes were acknowledged by Bard engineers during the design phase.[73] Bart acknowledged that polypropylene has several negative characteristics when compared to polyester mesh including: (1) more rigid and more aggressive for the tissue (the "barbed wire effect"); (2) Undoing when being stretched; (3) Detachment of particles or spikes when being cut.[74]

For the reasons set forth above, it is my opinion to a reasonable degree of medical certainty that the polypropylene mesh in the Bard Alyte product has several characteristics that make it improper to use in the body, including curling, cording, roping, particle loss, fraying, deformation and loss of pore size. These unwanted characteristics can lead to, among other

things, an increased inflammatory response (particle loss and fraying) and/or increased pressure on the anterior and posterior vaginal walls, or loss of pore size (roping or curling), and can lead to a multitude of injuries, including multiple erosion that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia, urinary and dedicatory dysfunction, vaginal scarring or shortening, wound healing problems, injury to ureters, infection and risk of pelvic abscess formation, and/or the need for additional surgery in the future.

Resultingly, the polypropylene in Bard's Alyte mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse in women, and Bard failed to act as a reasonable and prudent medical device manufacturer by making and selling its polypropylene mesh in a permanent prosthetic implant like Alyte. It has a defective design and is unreasonably dangerous. As stated by Ronald Bracken, Bard vice president of research and development from 2006 - 2011, it is "paramount" that medical devices are designed to ensure that the benefits outweigh the risks to protect the patient.[75]

Bard's Alyte mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse in the human body, because it degrades overtime. As a result, it is a defective design and is unreasonably dangerous.

Polypropylene for use as a permanent implant is not inert, despite the claims of Bard employees Bracken and Bigby to the contrary. Oxidation occurs during the synthesis of polypropylene mesh, which results in decreased molecular weight of the polymer chains, weakening and fracturing of the polypropylene fibers, and the release of toxic byproducts such as aldehydes, ketones, alcohols, peroxides, and free radicals that are neither inert nor benign. Upon implantation, this results in a cyclic cascade of maladaptive amplified foreign body immunologic response. Macrophage enzymatic response induces further degradation of polypropylene and the creation of additional free radicals, which further potentiates and amplifies the human body's chronic foreign body response. The resulting chronic inflammatory response not only leads to degradation, embrittlement, and fracture of the polypropylene fibers and mesh, but also generates an intensified fibrotic response resulting in abnormal scarring and contraction of the tissues surrounding the mesh.

In addition to the oxidative and degradative process that occurs prior to implantation, the manufacturing process of polypropylene mesh from resin involves the use of toxic chemical polymer additives such as aromatic stabilizers, colorants, photo initiators, antistats, antimicrobials, scavengers, and filters such as silicone oxide, calcium carbonate, talc, or titanium dioxide. In addition to the toxicity, these additives further enhance the chronic inflammatory response. Furthermore, the aromatic benzene ring compounds used in stabilizers have long been established as carcinogenic. Peer-reviewed literature regarding degradation/oxidation of polypropylene in the human body dates back to the 1960s and has been reported in numerous publications.[76] In his paper, "Characterization of Heavyweight and Lightweight Polypropylene Prosthetic Implants from a Single Patient",
Professor C. Costello reported that hernia mesh made of polypropylene oxidized and degraded as a result of the body's inflammatory reaction to the mesh. High magnification photographs showed cracking and peeling of the polypropylene fibers.[77]

Another article by A. Clave, "Polypropylene as a Reinforcement in Pelvic Surgery is not Inert: Comparative Analysis of 100 Explants", also displayed high magnification photos of polypropylene fibers from explanted meshes and, in this case, the meshes were explanted from women's pelvic floor tissue.[78] Heavyweight meshes showed even greater cracking than the lower density meshes, but according to Dr. Clave, all of the polypropylene explants examined (84) showed some degradation. Oxidation of the implanted mesh due to free radical attack through the synthesis of peroxides, superoxides, and hypochlorous acid during the chronic inflammatory phase was listed as just one potential cause for the oxidative degradation within the "septic environment" in which the pelvic meshes were placed. Bard was clearly aware of the Clave article and discussed it often. In a March 2010 email, less than two months after the Clave article was published, the Lead Development Engineer at Bard, Henry Holston, stated he needed to review the Clave article and requested it be sent to him.[79] Holston forwarded the Clave article on to senior Bard employees Bobby Orr, Laura Bigby, Adam Silver, and Magnus Pierson, stating "Interesting article…" Of note, Bobby Orr had recently been working on ways to change the pelvic mesh products Bard was marketing to make them safer and reduce patient complications. He wrote in a March 2009 memo: "Material selection to date is associated with various morbidities, including dyspareunia, pain, corrosion, extrusion, dehiscence, and abscess, to name a few. It is the appropriate choice of materials for a specific anatomical space as well as a repeatable surgical procedure that reduce failures and results in improved clinical outcomes."[79]

After Holstein forwarded the Clave article to Senior Bard employees, the director of marketing for women's health, Adam Silver, responded, "Very interesting. Enforces why we are working on low density, macroporous PP implants." He continued, "Is this the scarring and 'bridging fibrosis' that we speak about and are trying to reduce?" Not one of the senior Bard employees on the email chain expressed surprise, challenged the findings of Clave, or expressed any disagreement. Nor did any of the individuals express a need for Bard to conduct any studies to analyze degradation. The subject title of the email exchange was "Clave 2010 Polypropylene as a reinforcement in pelvic surgery is not inert." Later in 2010, just after Bard circulated the Clave article, senior engineers and executives at Bard were spending time and resources in evaluating mesh coating technology that would allegedly be "inherently more resistant to degradation"[80] to be "very intriguing for pelvic floor mesh coding" and worked to get in place legal contracts with the company promoting the technology. Roger Darois, Vice President, Research and Advanced Technologies, wrote in response to Bobby Orr, "The more I learn the more interested I've become."[80] Darois continued, "The added benefit of a mesh with much less potential for erosion, is worth a serious look." With additional analysis, Darois believed, "The expectation is that less fibrosis and scarring would result in less wound contracture and ultimately, less mesh shrinkage.[80]

This raises the question for then, in 2009, and now, in 2019, if Bard believed the mesh used in its mesh products did not degrade it in the human body, why were top engineers and executives at the company evaluating and expressing interest in mesh that would allegedly be resistant to degradation just months after the Clave article was circulated at Bard? To suggest that they did not believe so lacks any basis.

Two years later, in February 2012, Bard once again discussed the Clave article.[81] This time Claire Huntington, from the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, inquired as to Bard's knowledge of the Clave article. Ms. Huntington wrote: "Please find attached a paper suggesting that PP used in vaginal is not inert. Please could you provide me with your comments on this issue and also tell me about any testing you have carried out to show that the meshes used do not shrink."

Adam Silver and Bobby Orr, the same senior executives who discussed the Clave article in 2010, are once again included in the email exchange. Bard responds internally to the MHRA request by writing in part, "This is a curious question out of the blue at this particular point in time." Adam Silver then asks Bobby Orr and others to help respond to the MHRA request.[82] Bard, drawing on the resources of several different departments at Bard medical, responded to the MHRA a few weeks after getting the request regarding the Clave article. Scott Robirds, Vice President of Regulatory and Clinical Affairs at Bard signed the response. Mr. Robirds wrote in Bard's response that the MHRA "requested our comments on an article sent to us suggesting that polypropylene used in vaginal mesh is not inert. Attached please find Bard's response to the above requests.[83] Bard then writes, "Thank you for bringing this article to our attention." Bard senior employees of course had reviewed and circulated the article two years earlier, in 2010, and found it to be very interesting. Bard then lists several papers discussing the topic of mesh shrinkage or contracture, but none that discuss mesh degradation. Bard concludes their response to the Clave article by writing, "Testing carried out on our mesh: Bard has not conducted any testing to evaluate our synthetic vaginal meshes for mesh shrinkage." Not once in Bard's response does Bard deny the findings of the Clave article or comment on degradation of the polypropylene mesh used in its product. Bard does not take issue with any of the methodology or analyses used in the Clave article. It simply says it is aware of a few articles related to mesh shrinkage and has not performed any testing evaluating the mesh products for shrinkage.

Given the information available to Bard in the scientific and medical literature concerning the potential for degradation of polypropylene, it is my opinion to a reasonable degree of medical certainty that Bard should have conducted clinically relevant testing to determine if naturally occurring conditions in the vagina could cause polypropylene to degrade and if so, what the quantity and quality of the products of degradation would be, whether they would be released into the surrounding tissues and/or migrate in the woman's body, what the clinical implications for the woman would be, and whether some women's bodies would react differently to the mesh and the degradative process and its byproducts. This is especially true, given the fact that Bard knew degradation of its mesh could occur well before Bard ever brought Align to market. This was still true years later when Bard introduced Alyte. As early as 2002, Bard knew of the risk of degradation.[84] In a risk assessment for a Bard polypropylene mid-urethral sling completed in 2001 and approved by Bard's medical affairs director, product engineer and senior quality engineer in January 2002, Bard identified "degradation of device implanted" and "biodegradation" dangers associated with the properties of the device. It listed "permanent disability" as one of the consequences of degradation.[70] Additionally, it was known in the literature as far back as 1986 that degradation of prolene sutures was due to enzymatic action.[85] Interestingly, in spite of years of scientific literature, its own internal documents and reports from consultants that state that degradation of mesh occurs, Bard's

instructions for use (IFU) continued the entire time it sold meshes to be silent on the issue of warning of degradation. The Alyte product IFU makes no mention of degradation.

It is my opinion to a reasonable degree of medical certainty that the effect of chemical and biological degradation of the Bard mesh in a woman's tissue can and is most often likely to lead to a greater foreign body reaction, enhanced inflammatory response and scarring, which can lead to severe complications in patients, including the possibility of multiple erosions that can occur throughout one's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can preclude intercourse, infections, mesh rejection, urinary and defecatory dysfunction, pelvic scarring, injury to pelvic structures and/or the need for additional surgeries, among others. As a result, the polypropylene in Bard's mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse. Bard has the audacity in its Alyte IFU to state after all the years that its mesh products have been on the market that "The effectiveness of this product has not been validated by a prospective randomized clinical trial."

Bard's mesh products are not suitable for implantation in the human body as a permanent prosthetic device due to the lack of clinical studies supporting the safety and efficacy of these polypropylene products as therapy for urinary incontinence or pelvic organ prolapse.

This cavalier attitude on the part of Bard goes back to its earliest entry into the mesh market and continued until all of their mesh products were taken off of the market. The Bard approach appears to have been one of total complacency on this issue. As of May 2008, after the launch of the Align product, Bard discussed internally that they had "no data" supporting Align. Internal emails seem to suggest that Bard was watching for third parties to possibly develop data through their own "independent studies," saying, "We will just have to watch the journals."[86] The abject failure on Bard's part to engage in the scientific process, to formulate a hypothesis, to design experimental studies, and to test its product until safety and efficacy had been clearly demonstrated flies in the face of how medical products should be placed on the medical market. This attitude is pervasive and enduring—the Alyte IFU warnings still note the absence of any clinical trials regarding this product, a decade after Bard had done no clinical research to support Align. In October 2006, when the Align product was in development, a presentation to the Bard management board regarding discussions with doctors at the AUGS convention included the following passage: "Data, like always, is going to be very important with these things. We as a division need to step it up in this department. We always release products with no data."[87] The history of not having any clinical research persisted at Bard. In 2012, an email from Melissa Johnson, the Associate Director of Marketing wrote, "We have been selling Align for five years without data on the merits of the overall design and benefits of the product." Bard liked to claim that clinical data wasn't always necessary for their products because they have other means to determine safety. But these other means have inherent limitations, especially when compared to the value of clinical data. Internal documents show that Bard was aware of the limitations of this approach. When pressed by the FDA regarding safety data for Align, Bard admitted their means of testing a new sheath used on Align was inadequate and not representative of real-world in vivo applications seen in clinical use by doctors.[74] This corporate attitude persisted for over a

decade as Alyte was brought to market with no clinical data. Issues such as chronic pain, dyspareunia, shrinkage, degradation, deformation of the mesh (folding, bending, stretching, and cording), inflammatory actions and impact on sexual function, bladder and bowel function should have been studied by Bard prior to marketing Alyte. Outcomes and complications should have been resolved prior to marketing. Contingency plans should have been in place on how to manage these complications and how to inform physicians on how to deal with these complications. This is especially true, given Bard's own assessment of its knowledge and expertise in mission development or lack thereof.[88]

Bard had known for many years that the use of polypropylene mesh in the context of creating materials for the treatment of stress urinary incontinence and pelvic organ prolapse presented risks that could be reduced by the use of other available materials. As far back as 2001, Bard discussed internally that a proposed natural/synthetic hybrid device referred to as the "Bard Quick Sling" would minimize the risk of erosion and infection because there would be natural tissue under the urethra as opposed to polypropylene– such as is found in Ethicon's TVT device–which creates a "high risk of erosion and infection".[89] In 2002, Bard (through its employees, Doug Evans and Kenneth Butcher) applied for a patent for a "Natural Tissue Self Anchoring sling and Introducer System utilizing natural tissue instead of polypropylene. In its patent application, Bard referred to the synthetic mesh material then in use as treatment for stress urinary incontinence (polypropylene) and explained that it is "subject to a higher risk of causing the erosion of the patient's tissue than are natural materials. Furthermore, the synthetic mesh material has a higher risk of infection than natural material, probably because the mesh provokes a foreign body reaction from the patient's body. The synthetic material also tends to have a greater amount of scar tissue formation around the mesh fibers, instead of vascular ingrowth."[90] Bard went on to state that some "Doctors prefer not to use the synthetic materials due to the materials' higher potential for complications such as the occurrence of infection or foreign body reaction around the mesh or urethral or vaginal wall erosion due to the mesh. In some cases of erosion, mesh has been observed to unravel, creating a sharp 'fishing line' effect which can slice through the patient's tissue."[91] In another patent application from 2007 for a biologic material intended for rectocele repair and other soft tissue support, Bard again addressed the known dangers associated with polypropylene mesh implants, stating: "Patches for use in surgical procedures can be made from synthetic mesh material, for example polypropylene. Although easy to sterilize and inexpensive, synthetic material has a number of shortcomings. Perhaps most important, when synthetic material is used as a support member, the roughness of the synthetic mesh may lead to abrasion of the patient's tissue and that can cause infection and/or erosion of the tissue."[92] This reasoning seems just as valid years later when Alyte was marketed– then why did Bard abandon this approach?

Bard did learn during the decade between Align and Alyte that increasing pore size may have some merit—Alyte mesh has significantly larger pores (2.78 mm in the anterior/posterior vaginal flaps) than the Align product. But, as has been shown by Barone, the Alyte product does not maintain pore size under the stress of force, and the loss of pore size in vivo is partially responsible for the appearance of the known complications of mesh under force stress.

Bard's Alyte mesh is not suitable for its intended application as a permanent prosthetic implant for pelvic organ prolapse in the human body and is defectively designed and unreasonably dangerous because of the chronic inflammatory response/foreign body reaction it creates, resulting in fibrotic bridging, scar plate formation, and mesh encapsulation.

The human body has a natural and fairly predictable "host defense response" to any foreign objects placed inside it. Whether a small piece of debris or a mesh, the human body will send white blood cells to attack the invading structure, and if the products of inflammation cannot encapsulate or destroy the invader, whether the invader is bacterial or prosthetic implants or whatever, the acute initial inflammatory phase is followed by a chronic inflammatory phase. Therefore, with the placement of permanent surgical mesh in human tissues, there will be a chronic or permanent foreign body reaction to the implant as well as a chronic inflammatory response by the body.

The Bard Alyte IFU and Patient Brochures failed to adequately warn patients, and their surgeons, of the inherent risks from using this product.

The Alyte IFU states under the heading "Adverse Events" that "inflammation, sensitization, pain, dyspareunia, scarification, contraction, device migration and failure of the procedure resulting in recurrence of vaginal wall prolapse" are all possible. However, there are no listings in the IFU of permanent, lifelong, worsening and debilitating pain, lifelong risk of surgical repairs for erosions, severe or chronic inflammation, and device collapse under the stress of force causing fibrotic bridging, that the product can degrade, that polypropylene can be cytotoxic, cause severe erosion, or experience particle loss. In a classic paper from 2014, *Crosby et. al.*[93] reported on the successful surgical excision of vaginal mesh from 90 patients. Follow up data from 84 of these patients indicated that while mesh exposure was treated successfully in 95% of the patients, only 51% were relieved of their significant pelvic pain. A complication that has the potential for affecting over 50% of patients with incapacitating pelvic pain following the removal of a synthetic product should have been included in the IFU. Bard deviated from the standard of care required of a reasonable medical device manufacturer by failing to disclose adequately Alyte's known adverse reactions and risks to physicians and as a result has denied physicians and patients the ability to make an informed and proper decision regarding the use of Alyte.

DEPOSITION TESTIMONY REVIEW

Two Bard employee depositions have been provided for my review. The first is that of Ronald Bracken, Bard V.P. for Research and Development. In his deposition, he indicates that he was in this position from 2006 to 2011.[1] He indicated that he did not know why Alyte was initially marketed in Europe rather than the United States.[2] He stated that Bard did not have any plans for doing any prospective, randomized clinical trials in human subjects prior to marketing Alyte.[3] He indicated that the Alyte product had five desired product claims that Bard wanted to be able to make regarding Alyte: 1) reduced mesh load; 2) lightweight mesh to insure ease of conformity to pelvic tissue, thereby aiding in suture placement; 3) dimensionally stable knit; 4) polypropylene mesh with pore size of at least 75 microns; 5) minimal tissue reactivity.

He incorrectly states that, "I'm not sure that there's ever been data to link pore size to tissue reactivity."[5] There is a substantial body of evidence to the contrary, and it is perplexing that Mr. Bracken claims to be unaware of this. He also states that he believes mesh in the body is inert.[6] There is considerable evidence, including electron microscopy and pathology reports, including classic papers from Clave and Ostergard that convincingly refute this contention by Mr. Bracken. There may be some question about how much change occurs after placement of polypropylene in the human body, but there can be no doubt that it is not inert.

He indicates that he did not see the Material Safety Data Sheet (MSDS) for polypropylene until after he left Bard.[7] Given the extent to which Bard wrestled with the safety issues mentioned in the MSDS in some of its earlier product lines, it seems implausible that he could be unaware of this important piece of information regarding the raw product used to make the devices Bard was putting into the female pelvis. Regarding this issue, he further indicated that he was of the impression that Phillips Sumika put the warning on their raw polypropylene because they had not done any extensive research regarding the safety of polypropylene devices installed in the body, and they were using the MSDS as a means to avoid future litigation should any medical device company make a product using the polypropylene they manufactured inside a human body.[8] He did not cite any evidence to substantiate this claim about the Phillips Sumika package warning.

Mr. Bracken mistakenly asserted that polypropylene cannot degrade in the human body, and he couldn't remember seeing any studies regarding this topic.[9]

The paucity of clinical data collected by Bard prior to the launch of Alyte consisted of a retrospective study of European physicians who had used the Alyte product, and who were paid by Bard for participating in the survey. The other "clinical data" cited by Bard was a self-conducted literature review.[10] Bard had not conducted a single randomized, prospective clinical trial demonstrating the safety or efficacy of Alyte. Those physicians responding to the survey indicated that they had experienced a complication rate of 7.2% using the Alyte product in Europe. Mr. Bracken indicated that he did not know whether this was an "O.K." rate or not.[11]

Mr. Bracken indicated that he did not know that the Culligan data was not completed until 2013[12], several years after the Alyte product was launched. The Culligan study was received by the International Urogynecology Journal on June 10, 2013, accepted for publication on October 26, 2013, published online on November 22, 2013, and appeared in print in volume 25 in 2014 in the International Urogynecology Journal. The study only had 150 participants, and they were followed for only one year. The study was not blinded to either the patients or the researchers, and there was no control groups. At the time of the study, Dr. Culligan was a paid Bard consultant, and Bard provided the Alyte mesh used in the trial. The amount of Dr. Culligan's compensation for performing the trial is not listed.[13]

Mr. Bracken confirmed that Bard never studied the inflammatory response of the Alyte product in a human, but did rely on a study involving rabbits, who were studied after having been implanted for only 30 days.[14]

Until the time of his deposition, Mr. Bracken was not aware of the Barone study that investigated the response of mesh products to uniaxial loading. This study clearly demonstrated that the Alyte product pore size, shape, appearance, and response to force was significantly altered by loading.[14]

Mr. Bracken was asked to pull on an actual Alyte product during his deposition by Plaintiffs' counsel. Later, Defense counsel asked him to do the same thing, and asked him, "What happens when you let go?" Bracken answered, "It returns to its shape." The next question is, "And the pore sizes, do they return to the shape they were in after you pull tension on it as well?" Bracken's answer is, "Visually, it looks like they did." **The desired inference here is that Alyte will retain its pore size even after being stretched. Two major considerations refute this concept. The first is that the Y arms of Alyte are sewn onto the anterior and posterior surfaces of the vagina, and then the double thickness of the Alyte is anchored with suture into the periosteum of the sacral promontory. A device securely affixed with suture should not move significantly. Secondly, given that the Alyte device is secured to the (occasionally mobile) vagina, it is therefore still subject to the physiological forces generated in the female pelvis. Barone has elegantly demonstrated that after subjecting Alyte to variable amounts of force, consistent with those encountered routinely in the female pelvis, Alyte had the smallest pore size of mesh products tested. Barone continued, noting that "decreases in pore diameter enhance the host response and possibly increase the fibrous encapsulation of the mesh. Fibrous encapsulation and its potential contraction by resident myofibroblasts may induce pain after mesh implantation, which is one of the most common of mesh-related complications."[31]**

The other Bard employee deposition is that of Laura Bigby, who had the title of research and development project leader. She was deposed on August 30, 2019. She stated that the section of Bard that dealt with pelvic organ prolapse products is now basically "shut down".[15] She stated that Alyte development began in about 2008.[16] She added that she believes that she was the person at Bard who was most knowledgeable regarding the design and development of the Alyte device.[17] Bigby also stated the Bard company dogma that, "So, in general, the mesh is not shrinking. The mesh is placed in the tissue and the tissue is healing around it." She is asked again, "So it's your testimony here today the mesh itself doesn't shrink?" She answers, "Or very little if at all, yes."[18]

Later, she was asked, "...there were no human clinical studies that Bard undertook prior to the launch of the Alyte device, or were there?" she answered, "We again utilized the literature and the historical use of the device and predicate devices and information from other devices for that, but we did not conduct our own."[19]

She stated that the warning on the raw polypropylene cautioning against the use of polypropylene in the human body "never did appear in any IFU."[20]

A discussion in the deposition dealt with the issue of whether she felt polypropylene was not inert. She steadfastly stated that polypropylene was inert.[21]

She was questioned about the banding issue: "Is the risk of mesh banding a surgical misadventure or is that due to the quality of the material utilized to make the mesh?" and she answered, "I believe it's more along the lines of tensioning the mesh too tightly, perhaps a procedural application of a

mesh." She continued, "Again, you know, the mesh is not shrinking or contracting or moving. The mesh is going into the tissue and the tissue is integrating with the mesh."[22]

She agreed that the 2009 IFU did not mention the 2008 FDA bulletin,[23] nor did it discuss the potential need for more surgery following Alyte implantation,[24] nor does she recall Bard ever specifically training surgeons about how to implant the Alyte device.[25] She confirmed that there are no IFU warnings about nerve damage, dyspareunia, or urinary frequency or severity of complications.[26]

When asked about pathology reports, she stated that, "The mesh was integrated into the tissue. That the response to the mesh was fairly inert. That the mesh was in the tissue." [27]

The shrinkage issue was discussed again: "Did Bard have any scientific evidence available to it that would have allowed it to believe that mesh contraction or shrinkage was associated only with transvaginal placement of the pelvic mesh devices versus abdominal placement?" She responded, "…we did study mesh and mesh contraction of the lack of it in various studies, and the mesh is not shrinking. It's the tissue in the healing process. The mesh is not actually shrinking though."[28]

She thought that the Culligan study lasting for only one year was long enough to assess the safety of the Alyte product.[29]

GENERAL CAUSATION

Bard's Alyte product was cleared for the market on April 11, 2011 by the FDA 510(k) process. On page 2 of the Alyte IFU, Bard states, "The effectiveness of this product has not been validated by a prospective randomized clinical trial." However, mesh products, and Alyte, which Bard chose not to test or to evaluate for safety or effectiveness or long-term harmful consequences, or subject to clinical trials has been investigated by the worldwide urogynecological academic community. I conducted a literature search of pelvic mesh products to see what knowledge and information was available. I looked primarily at articles from the last decade, required that the articles be in English, and looked primarily at review articles. The following observations are made by these studies, and constitute some of the requirements and findings that were made by the FDA when it directed mesh product manufacturers to have substantially better data and documentation and clinical trials to keep mesh products on the market (PHN 2008 and 2011).

MESH COMPLICATION RATES ARE TOO HIGH

For many women, the most distressing consequence of Alyte implantation has been the onset of complications. "Complications after sacrocolpopexy appear to increase over time with cumulative incidents of mesh exposure at 10.5% over a seven-year period."[94] *Liang et. al.* note that while Alyte is a type 1 large pore mesh, it is uniquely subject to stiffness and a loss of porosity from the normal forces occurring in the pelvis. This is considered to be associated with the knit pattern of the mesh, and when the porosity is lost, then the mesh is subject to roping and an increased inflammatory response. "In this way, prosthetic devices that are significantly stiffer than the native tissue they are designed to augment or associated with an increased rate of long-term

complications."[94] "When subjected to repetitive loading, prolapse meshes tend to permanently deform and this deformation is irreversible."[95] "When loaded, prolapse meshes are also impacted by the applied boundary conditions (i.e. the way in which forces/displacements are applied and how movement is allowed/restricted). Sutures used to attach prolapse mesh to the vagina and the pelvic sidewall or sacrum essentially act as point loads. Applying point loads during uniaxial loading results in out-of-plane deformation resulting in mesh wrinkling, buckling and/or folding."[94] "In the areas where in the mesh has wrinkled, there is an increased amount of material and it is likely that foreign body response to the mesh in this area is enhanced."[94] "Given the importance of pore size and porosity, the reduction in pore size (less than 1 mm), porosity, and effective porosity all potentially decrease the biocompatibility of synthetic mesh. This may also lead to an increased risk of bridging fibrosis, inflammation, poor tissue integration, and fibrosis, which may ultimately result in poor patient outcomes.[94] For the future, *Liang et. al.* argue for preventing the reduction in pore size and loss of porosity in response to loading, to allow for adequate tissue in-growth and integration, possibly reducing the risk of mesh-related complications.[95] However they note that "*Current polypropylene prolapse meshes are associated with persistent rates of complications; particularly mesh exposure and pain.*"[94] (Italics mine)

ALYTE MESH USE RESULTS IN CHRONIC PAIN AND DYSPAREUNIA

Further consideration of the pain issue is provided by *Tootzs-Hobson et. al.*, writing earlier this year. They state, "…it is acknowledged that some women have suffered significant complications in association with their surgery." "Secondly, there has been a failure to recognize the severity of any adverse impact these complications have on these women," and, "The most controversial complication however is pain."[95] They delineate four different manifestations and causes of pain. The first is direct injury, which occurs at the time of mesh implant and is disproportionate to the operation. If recognized early, such as inability to walk or bear weight, it usually can be resolved easily by a return to the operating room and can be corrected without long term consequences. Second is a delayed presentation, some 6-12 weeks following surgery, likely related to nerve compromise, due to the mesh passing too close to a nerve or tethering of the tissue surrounding the nerve to the mesh. These types of pain may resolve with trigger point injection or re-operation in some 60-90% of cases.[95] Third, the longer term delayed presentation may be associated with the patient having a pre-existing condition, "such as fibromyalgia associated with pain as part of their symptomatology."[95] These patients should be warned that surgery to correct their condition may not be successful. Fourth, are those deemed "late presentation" occurring years following mesh implantation. These may include erosion and a poorly defined group with "no obvious abnormality."[95] Ultrasound may delineate the problem, but this is an as yet poorly understood or defined entity, and among the most difficult to treat. Many of these women go on to experience debilitating, life altering pelvic pain that is impossible to alleviate fully.

ALYTE MESH USE RESULTS IN THE NEED FOR MORE SURGERY

Welk et. al., in 2015, identified 59,887 women who had surgery for SUI. They determined "that 1 in 30 of these women may require a second procedure for mesh removal or revision and that 37% had an increased likelihood of having a complication."[96] More specifically, they looked at the complication issue as it relates to the volume of surgery performed by the operating surgeons. High volume surgeons performed more than 16 procedures annually, placing them in the 75th percentile

or greater compared to the low volume surgeons. The high-volume surgeons were also less likely to perform a simultaneous hysterectomy and were more likely to perform the surgery in an academic medical center. Patients who were operated on by low-volume surgeons were at an increased risk (37%) for mesh removal or revision. The authors also "demonstrated that patients undergoing two or more mesh-based procedures for urinary incontinence was associated with an almost 5-fold increased risk for complications. This novel finding should temper the enthusiasm of case series that suggests that the use of multiple synthetic slings is safe and efficacious."[96] Welk and his colleagues also noted that, "The additional dissection, trauma to the pelvic nerve plexus, and postoperative change to the vaginal anatomy may account for the increased risk for complications observed with a simultaneous hysterectomy and mesh-based procedures for SUI."[96] *In its IFU regarding Alyte, Bard did not mention the risk of having a simultaneous hysterectomy or having the surgery performed by a low volume surgeon.* (Italics mine)

ALYTE MESH USE SHOULD BE RESTRICTED

In a major review article, Chapple and his colleagues conclude that, "Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centers."[97] (Nowhere in its IFU did Bard make such a suggestion.) Chapple and his associates continue by noting that, "The risk of abuse of the mesh increases with that surface area and, thereby, its increasing density."[97] They also note that surgeons should be adequately experienced in the management of SUI and POP, and should have all the therapeutic options available. Patients should be appropriately assessed and counseled prior to making a decision to undergo surgery, regarding the experience of the surgeon and results of the proposed technique."[97] (Bard did not stipulate any of these conditions in its IFU.)

ALYTE MESH DOES NOT PREVENT LATERAL CYSTOCELE

Liu et. al., compared transvaginal mesh placement to laparoscopic sacrocolpopexy for prolapse repair. They noted that "because the anterior compartment was repaired by merely anchoring the anterior leaf of a Y shaped mesh along the vaginal length, the recurrence of the cystocele was most likely a result of the lateral defects of a cystocele that were not repaired by this technique."[99] Bard Alyte does not cover the lateral aspect of the vagina it is designed to support, but only the anterior and posterior surfaces. It follows that lateral defects where no mesh has been placed would be the most likely to herniate and produce the observed lateral defects. They also said, "Our results suggested that the new lightweight meshes may have a weaker suspension force than the original ones, which cannot withstand the excessive load of a prolapsed uterus indefinitely and eventually cause recurrent uterine prolapse."[99]

LIGHTWEIGHT MESH WITH INCREASED PORE SIZE IS NOT A PANACEA

Weyhe et. al. compared light weight to heavy weight polypropylene meshes and noted "Worse biocompatibility of lightweight mesh compared to heavyweight mesh. Thus, the amount of an implanted mesh was not the main determinant of biocompatibility, (expressed as successful in corporation and diminished foreign-body reaction) but the size of the pores. This is consistent with the findings of Barone, cited above, which indicates that light weight mesh is not able to

maintain its porosity when subjected to the stress of force, and the resultant curling and roping results in an increased inflammatory response.[100] Barone has elegantly demonstrated that after subjecting Alyte to variable amounts of force, consistent with those encountered routinely in the female pelvis, Alyte had the smallest pore size of mesh products tested. Barone continued, noting that "decreases in pore diameter enhance the host response and possibly increase the fibrous encapsulation of the mesh. Fibrous encapsulation and its potential contraction by resident myofibroblasts may induce pain after mesh implantation, which is one of the most common of mesh-related complications.

THE LONG-TERM HOST RESPONSE TO ALYTE MESH IS UNKNOWN

Patel et. al. published a review article concerning the issue of polypropylene mesh and the host response. They noted, "Whether any one product is superior remains unclear, as evidence-based outcome and safety data lag far behind the introduction of medical implants. As surgeons strive to improve outcomes, they offer patients these new innovations without the benefit of knowing long-term outcomes and safety." Additionally, they note, "The United States FDA and the UK's National Institute for Health and Clinical Excellence have issued warning statements regarding the use of synthetic mesh in vaginal surgery for pelvic floor reconstruction in light of the absence of level one evidence supporting its efficacy and safety.[101] Their observations continue, "The matrix formation is aided by the immune response that is triggered by injury to vascularized connective tissue. The matrix is rich in cytokines, chemoattractants, and growth factors important for enhancing cellular activity and the subsequent activation and proliferation of other mediators in the early wound-healing response. In other words, the matrix lays the framework upon which subsequent phases will respond."[101] Additionally, they note, "The process of tissue ingrowth into the mesh is a result of the local inflammatory response upon implantation," and, "Whereas inflammatory reaction is necessary for connective tissue deposition, a state of enhanced immunological activity may also be the source of postoperative complications."[101]

As a gynecological surgeon who has operated on scores of women for mesh complications, I concur with many others who have made the observation that removing pelvic mesh from the vagina or the pelvic cavity is analogous to removing concrete from a reinforcing bar with a hammer and chisel. Scalpel blades and scissors quickly become dull, clamps lose their grip, and the surgeon's fingers and hands feel beaten at the end of these cases. The density, toughness, and impenetrability of the scar tissue surrounding pelvic mesh is unlike that I have seen in any other pelvic condition.

It has always seemed highly implausible to me that a mesh used for abdominal wall hernia repair should have been allowed to be the predicate device for the vaginal meshes to enter the medical marketplace. The anatomic, physiologic, neurosensory, and functional characteristics of these two body sites could not be more different. To assume, or even to consider, that they may react in a similar fashion to the same implanted synthetic material boggles the imagination. Citing the work of *Pierce et. al.*, Patel notes that, "Implantation of the same material into different anatomic locations—abdomen and vagina-resulted in different histologic responses. Tissues surrounding vaginal grafts have significantly higher scores for inflammation and neovascularization and lower scores for fibroblastic proliferation than tissues surrounding abdominal graphs. Clearly, anatomical factors need to be considered when interpreting and applying study findings to any

particular clinical situation.[101] Patel notes that, "Some authors suggest an infected mesh as being a key component in de novo urge symptoms after placement of a midurethral sling. In that study 83% of patients with urge symptoms have bacteria identified in the excised tissue, compared to 5% in control.[101] They conclude with the caveat, "Despite its long-term and widespread use, there is little known about the tissue response to polypropylene in the human vagina."[101] The cavalier attitude that Bard has demonstrated for years in bringing pelvic support products to market without double-blind, randomized clinical trials to demonstrate clinical safety and efficacy is made manifest in the problems experienced in women who have had Bard Alyte placed in the pelvis because other mesh products seemed to work for abdominal wall hernia repair.

ALYTE MESH SHRINKS AFTER IT HAS BEEN IMPLANTED IN THE PELVIS

Svabik and his co-workers hypothesized that mesh associated complications may be linked to mesh shrinkage. They assessed (36) patients who had undergone mesh implantation by measuring the length of the implanted mesh on the day of surgery, and then four days later they performed a vaginal ultrasound examination to measure the length of the implanted mesh, and they measured the length of the mesh again 3 to 5 months later following the initial surgical procedure. They discovered that there was a significant difference in mesh length determined before and four days following surgery, from 57.1 to 48.3 mm ($P<0.0001$), indicating possible shrinkage or retraction.[102] The degree of shrinkage observed by us (approximately 15%) agrees with data from experimental animal studies using a similar type of mesh, where shrinkage of between 15% and 28% of the original area was described. Other authors have recently presented long-term ultrasound data suggesting a linear decrease in mesh dimensions, implying ongoing contraction/retraction of mesh. They conclude that, "the main means of improving mesh appearance and dimensions should be a change in surgical technique and mesh size in order to allow the mesh to be implanted flat and well spread out, anchored to underlying tissues in order to prevent immediate postoperative folding."[102] This is a noble goal, but even when the surgery is performed skillfully and well, there is no guarantee that there will not be a pronounced inflammatory response.

I am aware that both of the Bard employees deposed in this case have taken the specious stance that they do not believe that Alyte mesh "shrinks". This is the Bard corporate position on the topic, but it is absolutely wrong. Multiple authors agree with the findings of Svabik in the above paragraph. Perhaps this is a question of semantics, but the fact is that in those cases where it is necessary to operate on a patient to remove pelvic mesh, whether from the vagina or abdominally from the pelvis, the mesh and the tissue surrounding it is never as long or wide as it was on the day it was implanted. It is certainly thicker, because the mesh is invariably ensconced in a tight web of connective tissue. The inflammatory response to this foreign tissue invariably bunches the mesh in thick scar tissue and removing this (usually painful) mass of mesh and scar tissue is almost invariably a tedious, challenging, and potentially dangerous operative procedure. For Bard not to mention or acknowledge this is beyond the pale.

ALYTE MESH COMPLICATIONS IMPACT PATIENTS' QUALITY OF LIFE BY CAUSING EROSIONS

The number and types of complications resulting from the use of synthetic mesh for pelvic organ prolapse are substantial. Bako and Dhar delineate these in detail. "The use of synthetic mesh to correct apical, anterior and posterior vaginal wall prolapse is not without complications." They continue, "There is a paucity of high-quality evidence to support the routine use of synthetic measures for augmentation of anterior and posterior vaginal wall and apical repairs." "It is important to note that the use of synthetic mesh is not without complications and mesh-related complications could have significant impact on the quality of life of sufferers, limit their use, and add to the cost of health service." "There is variation in the timing of mesh erosion. Mesh erosion has been reported as early as six weeks and as late as seven years after surgery." "The use of a low weight, monofilament, large-pore size polypropylene mesh coated with a hydrophilic film for vaginal prolapse repairs was associated with a 10% erosion rate when concomitant hysterectomy or trachelectomy was performed and a 4% erosion rate if the uterus was preserved or if the procedure was performed after a previous hysterectomy." They conclude, "routine use of synthetic mesh and vaginal reconstructive surgery outside of clinical trials cannot be recommended until robust data on its safety and efficacy emerge."[103]

THERE ARE SAFER AND MORE FEASIBLE DESIGN ALTERNATIVES TO THE BARD ALYTE PRODUCT

There were multiple safer alternatives to the design of the Alyte product that would have been not only safer but more effective. First and foremost, Bard used industrial grade polypropylene as opposed to medical grade polypropylene. For the reasons previously stated in this report, the risks of industrial and inherently less stable polypropylene greatly outweighed the safer alternative of medical grade polypropylene. Second, native tissue repair using the patient's own tissue is much safer with most if not all of the risks related to mesh being eliminated. It is also just as effective if not more effective when the surgery is performed by a skilled surgeon. Third, pelvic organ prolapse products consisting of either cadaveric or procine material are also superior to polypropylene products such as Alyte in that they also do not have many of the unsafe complications and risks associated with products like Alyte.

ALYTE MESH USE IS NOT JUSTIFIED FOR USE BASED ON RESULTS AND COMPLICATION RATES

Finally, in a major review article, the PROSPECT paper evaluated (35) referral hospitals and surgery performed by (65) gynecological surgeons. This "consisted of two pragmatic, parallel-group, multicenter, randomized, controlled trials." The authors conclude that, "Augmentation of a vaginal repair with mesh or graft material did not improve women's outcomes in terms of effectiveness, quality-of-life, adverse effects or any other outcome in the short-term, but more than one in ten (10) women had a mesh complication." They cite a Cochrane review containing thirty-seven (37) trials, noting the "quality of current evidence remains very low to moderate, due to poor reporting of study methods, inconsistency and imprecision". They continue, "Two years after surgery, we show that women do not benefit from having their first prolapse repair (either standard anterior or posterior repair) reinforced with synthetic mesh or biological graft, either in terms of

prolapse symptoms or anatomical cure." They assert, "Our large, rigorous study offers strong, clinically relevant evidence for the alternate view that mesh or grafts are unlikely to be useful in terms of improving any symptoms of pelvic-floor dysfunction or women's quality-of-life up to 2 years after surgery. Some women had treatment for mesh complications, although most mesh exposures were small and asymptomatic. Further long- term follow-up will ultimately determine whether the use of mesh or grafts in vaginal prolapse repair provides any long-term benefits." In the discussion section of their paper, they note that, "There was no evidence of a significant difference at one year in the primary outcome after transvaginal prolapse surgery with or without synthetic, non-absorbable mesh or biological graft material to reinforce the repair." Additionally, they state that, "The overall mesh complication rate in women who actually received synthetic mesh--either in the mesh trial or concomitantly--was 12%." They noted that, "given that recurrent prolapse requiring repeat repair occurs on average (12) years after a first standard repair, ongoing follow-up is essential to determine whether mesh or graft repairs might yet prove more durable in the long term, and to identify further adverse sequelae of mesh or graft insertion." They conclude by noting that, "The PROSPECT study showed that augmenting a primary transvaginal anterior or posterior prolapse repair with a non-absorbable synthetic mesh or biological graft confers no symptomatic or anatomical benefit to women in the short term. More than one in 10 women had a mesh complication."[104]

A CONTRARY OPINION SUPPORTING ALYTE USE

There is a study by *Culligan et. al*. that supports the use of the Alyte product. However, there were only 143 patients available for follow-up for only one year following surgery, there was no control group, and it was not blinded to either the patients or the implanting surgeon. Bard provided the mesh used for this study and the lead author is a paid consultant for Bard.[98] It was not published until 2014, long after Alyte came onto the market.

CONCLUSIONS

Bard has marketed and sold the Alyte product despite the fact that it has numerous characteristics that make it unsuitable for implantation in a woman's body and is defectively designed and unreasonably dangerous. These characteristics include, but are not limited to the following: (1) toxicity as per the manufacturer: (2) propensity to rope, cord, curl; (3) propensity to fray and have particle loss; (4) propensity to degrade; (5) propensity to have a chronic foreign body/inflammatory response; (6) propensity to have fibrotic bridging leading to scar plate formation and mesh encapsulation; and (7) propensity to have shrinkage/contraction of the encapsulated mesh. Not only did Bard sell a product which should have never been put into the female pelvis, it failed to inform physicians and their patients about numerous risks associated with the product despite the fact that they knew these risks before the product was launched. It is obvious that the horrible results described were knowable. The studies cited demonstrate that beyond any reasonable question. Bard simply decided to market an untested and unproven product to see what would happen. This failure by Bard has robbed women of their ability to make a proper informed decision with their physician about whether to have a permanent medical device implanted into their body. Finally, while keeping this information from women, and/or failing to perform the studies that would demonstrate the problems, Bard marketed Alyte with promotional pieces that did not disclose key conflict of interest information or the true complication rates of its product. As a result

of these failures as fully set forth in this report, the Alyte product has caused and will continue to cause a multitude of injuries in women, including the possibility of multiple erosions that can occur throughout a woman's lifetime, chronic and debilitating pelvic pain, recurrence, worsening incontinence, dyspareunia that can be chronic, wound infection, rejection of the mesh, sexual dysfunction, urinary and dedicatory dysfunction, vaginal scarring, wound healing problems, pelvic abscess formation, risk of infection, direct trauma to organs and tissues, nerve injuries, and/or the need for additional surgery.

For the reasons set forth throughout this report in my opinion, to a reasonable degree of medical certainty, bard failed to act like a reasonable medical device manufacturer and designed and sold a defectively designed and unreasonably dangerous product, which directly led and caused and contributed to cause the injuries and damages in the new rated above in thousands of women.

All of the opinions that I have and will give are to a reasonable degree of medical certainty. I understand that discovery is still ongoing in this case and I reserve the right to amend my opinions as further information is provided in any form including, but not limited to corporate documents, depositions, and the expert reports of both Plaintiff and Defense experts in new medical and scientific studies and literature.

Keith O. Reeves, M.D.

BIBLIOGRAPHY FOR GENERAL EXPERT REPORT ON ALYTE

1. AVA2El281085
2. *Cisson v. Bard* 8/7/13 Trial Transcript, 64:6-8; 69:11-70:4
3. *(Cisson v. Bard* 8/7/13 Trial Transcript, 62:15-71:23; 101:25-102:13).
4. AVA2E8262834
5. AVA2E8262832
6. AVA2E8262831
7. AVA2E8766668
8. AVA2E8766668
9. AVA2E8766667
10. AVA2E8766667
11. AVA2E9866668
12. AVA2E8766668
13. Kassem, M., Community Oncology, Volume 7/Number 4/April 201O; Mehrotra, PK, Hernia, 2006 10:192-194
14. Kwon S., et al, Female Pelvic Med Recontruct Surg, Volume 17, Number 4, July/August 2012
15. Ahuja, S., et al, Gynecol Surg (2011) 7:217-221
16. Ben-Izhak, 0., et al, Am J Surg Pathology, Issue: Volume 23 (11), 1999, p. 1418
17. FDA 510(k) Summary of safety and effectiveness information for Alyte
18. FDA Bulletin of 4/16/19; Urogynecologic surgical mesh implants
19. Barone WH et al. Am J Obstet Gynecol 2016;215: 326.e1-9
20. AVA2E0121601
21. AVA2E0001303
22. BRAKEN DEPO PG.46, LINE 15 –PG.47,LINE 8.
23. BRAKEN DEPO PG 47, Line 25—Pg.48,Line 3.
24. BRAKEN DEPO PG 62, Line 4 , Pg 12
25. BRAKEN DEPO PG Pg 153, Line 4-10
26. AVA2E7497195
27. Freitag depo. Pg 79, line 1-6.
28. AVA2E7497194
29. AVAMDL2_00448
30. Braken Depo. Pg.81,Line 16-2231.
31. Liebert T, ChartoffR, Costgrove S, "Subcutaneous Implants of Polypropylene Filaments," J Biomed Mater Res. 1976 (10:939-951); Williams D, "Review ofBiodegradation of Surgical Polymers,". J Materials Sci, 1982 (17:1233-1246); Oswald, HJ, Turi, E, "The Deterioration of Polypropylene By Oxidative Degradation," Polymer Eng Sci, 1965 (5:152-158).
32. Costello et al., Characterization of heavyweight and lightweight polypropylene prosthetic mesh explants from a single patient.
33. Clave A. polypropylene as a reinforcement and pelvic surgery is not inert: comparative analysis of 100 explants." Int Urogynecol j.2010;21:261-270.
34. AVE2E0900248

35. AVA2E0087159
36. AVA2E8310677, AVA2E8310682, AVA2E8751394
37. AVA2E8647113
38. AVA2E8428025
39. AVA20130034
40. Jongebloed, WL, "Degradation of Polypropylene in the Human Eye: A SEM Study," Doc Ophthalmol., 1986 64(1:143-152)
41. AVA2E751442
42. AVA20130034
43. AVA2E8049153
44. AVA2E039193
45. AVA2E1095328
46. AV31095328-5329
47. AVA2E6681921-1922 (Bard patent application for "Expandable Tissue Support Member and Method of Forming the Support Member").
48. Crosby E.C. et al. Symptom Resolution After Operative Management of Complications from Transvaginal Mesh. Obstet Gynecol 2014; 123:134-39.
49. Bracken depo p.1
50. Bracken depo p. 23
51. Bracken depo p. 23-24
52. Bracken depo p. 35
53. Bracken depo p. 38
54. Bracken depo p. 39
55. Bracken depo p. 43-44
56. Bracken depo p. 46-47
57. Bracken depo p. 61-62
58. Bracken depo p. 66-67
59. Bracken depo p. 72
60. Bracken depo p. 79
61. Int Urogynecol J 2014; 25:731-735-62. Barone WR et al. Am J Obstet Gynecol 326e1-e9.Sept 2016
62. Bigby depo p. 9
63. Bigby depo p. 20
64. Bigby depo p. 22
65. Bigby depo p. 27-28
66. Bigby depo p. 51
67. Bigby depo p. 53
68. Bigby depo p.76-77
69. Bigby depo p. 88
70. Bigby depo p. 92
71. Bigby depo p. 94
72. Bigby depo p. 97
73. Bigby depo p. 100
74. Bigby depo p. 109-110

75. Bigby depo p. 115
76. Bigby depo p. 125
77. Liang R et al. Exploring the basic science of prolapse meshes. Curr Opin Obstet Gynecol 2016;28:413-19.
78. Toozs-Hobson P et al. Managing pain after synthetic mesh implants in vaginal surgery. Euro. J Obstet Gynecol Reprod Biol 2019;234:49-52.
79. Welk B. et al. Removal or Revision of Vaginal Mesh used for the Treatment of Stress Urinary Incontinence. JAMA Surg. 2015;150:1167-75
80. Chapple C.AR. et al. Consensus Statement of the European Urology Association and the European Urogynecological Association on the use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence. Euro. Assn Urol. 217;72: 424-31.
81. Liu C-K et al. A comparative study of laparoscopic sacrocolpopexy and total vaginal mesh procedure using lightweight polypropylene mashes for prolapse repair. Taiwanese J Ostet Gynecol 2010;53:552-58.
82. Weyhe D. et al. Experimental comparison of monofile lightweight and heavy polypropylene meshes: less weight does not mean less biological response. World J Surg. 2006;30: 1586-91.
83. . Barone WR et al. Textile properties of synthetic prolapse mesh in response to uniaxial loading. Am J Obstet Gynecol 2016;215:326e1-9.
84. Patel H et al. Polypropylene mash and the host response. Int J Urogynecol 2012;23:669-679.
85. Svabik K et al. Ultrasound appearances after mash implantation-evidence of mesh contraction or folding? In t Urogynecol J 2011;22:529-33
86. Bako A and Dhar R. review of synthetic mesh-related complications in pelvic floor reconstructive surgery. Int J Urogynecol 2009;20:103-11.
87. Glazener C.MA. et al. , Graft, or standard repair for women having primary transvaginal anterior or posterior compartment prolapse surgery: two parallel-group, multicenter randomized, controlled trials.(PROSPECT). Lancet 2017;:381-392.
88. Culligan PJ et al. Subjective and Objective Results one Year after Robotic Sacrocolpopexy Using a Lightweight Y Mesh. Int J Urogynecology 2014;25:731-35.

DIPLOMATE, AMERICAN BOARD OF
OBSTETRICS & GYNECOLOGY
FELLOW, AMERICAN COLLEGE OF
OBSTETRICIANS AND GYNECOLOGISTS

PHONE (713) 797-9498
FAX (713) 797-0661
E-Mail keithr@bcm.tmc.edu

KEITH O. REEVES, M.D.
SCURLOCK TOWER, SIUTE 2100, 6560 FANNIN
HOUSTON, TEXAS 77030

CURRICULUM VITAE

I. General Biographical Information
Keith O. Reeves
Date of birth: July 2, 1944. New Orleans, Louisiana
Citizenship: USA
Eagle Scout, 1962

Education:
Undergraduate: The University of Texas at Austin
B.A. cum laude. 1962-1966
Medical Education: Baylor College of Medicine, Houston, Texas
M.D. 1966-1970
Internship: Baylor Affiliated Hospitals, Houston, Texas
Straight Pediatrics 1970-1971
Residency: Baylor Affiliated Hospitals, Houston, Texas
Obstetrics and Gynecology 1973-1976
Chief Resident, 1975-1976

Military Experience: Captain, U.S. Air Force 1971-1973. Flight Surgeon & Chief, Aerospace Medicine Office, Sheppard Air Force Regional Hospital, Wichita Falls, Texas.

Academic Appointments:

Clinical Professor Emeritus of Obstetrics and Gynecology
Weill Medical College of Cornell University, July 1, 2017

Emeritus Physician, Department of Ob/Gyn, Houston Methodist Hospital, January 2014

Founding Medical Director, Methodist Center for Restorative Pelvic Medicine, May 2006-December 2013

Clinical Professor of Obstetrics and Gynecology
Weill Medical College of Cornell University, April 2005-July 2017

Clinical Associate Professor, Department of Obstetrics/Gynecology,
Baylor College of Medicine, 1986-2005.

Clinical Assistant Professor, Department of Obstetrics/Gynecology,

Baylor College of Medicine, 1978-1986.

Clinical Instructor, Department of Obstetrics/Gynecology,
Baylor College of Medicine, 1976-1978.

Honors/Awards:

Voluntary Faculty Member of the Year, 1997-1998 & 2000-2001 Baylor College Medicine, Department of Obstetrics and Gynecology
Diplomate; American Board of Obstetrics and Gynecology, certified 2/15/1979. Voluntarily recertified, American Board of Obstetrics and Gynecology, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007,2008, 2009, 2010, 2011, 2012, 2013, 2014
Recipient, Air Force Commendation Medal, 1974
Member, Wyeth Speakers' Bureau, 1997-2009
Member, Procter and Gamble Speakers' Bureau, 2004-2005
Recipient, "Golden Forceps Award" 1/03 for resident and student teaching, Dept Ob/Gyn, Baylor College of Medicine
Listed in "H" Texas magazine 9/03, 4/05, 3/06 and 3/07as one of Houston's Best Obstetricians/Gynecologists
Listed in Texas Monthly magazine in 12/05, 12/06, 12/07, 12/08, 12/09 and 12/10, 12/11, 12/12, 12/13 as one of Texas' "Super Docs"
Listed as one of the "Best Doctors in America" 2005-2006, 2007-2008, 2009-2010, 2011-2012
Permanent Physician Member, Methodist Hospital System Board of Directors, effective 7/1/09—12//20/13

II. Research Information

National and State Scientific Participation:

Fellow, American College of Obstetricians and Gynecologists, 1979-2013, Life Fellow 2014
Member, Central Association of Obstetricians and Gynecologists, 1981-2013
Member, Texas Association of Obstetricians and Gynecologists, 1976-2013
Member, The American Urogynecologic Society, 2006-2014, Life Member 2015
Member, Executive Council, Texas Association of Obstetricians and Gynecologists 1980-1983

Local Scientific Participation:

Member, Executive committee of the Medical Staff, Methodist Hospital, 1981-1983
Member, Rules and Bylaws committee, Methodist Hospital, 1984-1991
Member, Board of Directors, Planned Parenthood of Houston and Southwest Texas, 1989-1991
Member, Executive Committee, Houston Gynecological and Obstetrical Society, 2002-2009
Treasurer, Houston Ob-Gyn Society 2004
Secretary, Houston Ob-Gyn Society 2005
Vice-President, Houston Ob-Gyn Society 2006
President-Elect, Houston Ob-Gyn Society 2007
President, Houston Ob-Gyn Society 2008

Chairman, Methodist OB-GYN Audit committee, 1980-1985
Chairman, Methodist Ob-Gyn Service committee, 1986-1989
Member, Methodist Abdominal/Pelvic Surgery Quality Management Committee, 1997-2000
Member Medical Executive committee, MethodistCare HMO, 1997-2002
Member, Quality Improvement Council, MethodistCare HMO, 1997-2002
Member, Credentials committee, MethodistCare HMO, 1997-2002
Member, Medical Records Committee, The Methodist Hospital, 2001-2002
Member, Chief of Service Review Committee, The Methodist Hospital, 2001, 2002
Medical Director, Gynecology Unit, The Methodist Hospital, 2005-2010
Founding Medical Director, Methodist Center for Restorative Pelvic Medicine, 2007-2013
Member, Methodist Hospital System Board of Directors, 2009-2014
Member, Methodist Board Quality and Safety Committee, 2009-2014
Member, Methodist Board Executive Committee, 2009-2014
Member, Methodist Board Spiritual Care Committee, 2009-2014

Presentations:

The Power Morcellator—Machinations, Money and Madness. Presentation to Williams, Kherkher, Hart, and Boundas. March 20, 2015, Houston, Texas.

Vaginal Mesh—the Legal Consequences. Presentation to Aylstock, Bailey, Burnet, Junell, Potts, and Witkin. February 26, 2015, Houston, Texas.

Mesh in the vagina. The anterior compartment. Methodist combined Ob/Gyn and Urology Grand Rounds, with Sophie Fletcher, MD & Ricardo Gonzalez MD of Methodist Urology,, 1/4/12

Mayer Rokitansky Kustner Hauser syndrome-A brief review and technique for surgical correction. Methodist Ob/Gyn Grand Rounds, with Tue Dinh, MD, plastic surgery service.,10/5/11

Hormones and the Female Singing Voice. Invited Guest Lecturer, Aspen Music Festival, Aspen, Colorado, 8/5/11

Redefining Prolapse Surgery: The Graft Era. A Multidisciplinary Approach to the Pelvis in 2006. The Houstonian Hotel. Houston, Texas November 11, 2006

Pre-Term External Cephalic Version in an Outpatient Environment. Moyne T. Kornman, Kay T. Kimball & Keith O. Reeves. Presented at the Central Association of Obstetrics and Gynecologists, Memphis, Tennessee, 10/13/94.
A Simple, Inexpensive Device for Teaching the “Loop” Operations. Keith O. Reeves, Amy E. Young, & Raymond H. Kaufman. Presented at the Association of Professors of Obstetrics and Gynecology, 2/21/99, San Diego, California.

Publications:

Toy E, Harms K, Papasakelariou, C, Reeves, K. Case Files in Gynecological Surgery. McGraw Hill , New York, NY. 2011.

Reeves, KO et al. Candida peritonitis in a quadriplegic; treatment with amphotericin B. South Med J 1972 Mar; 65 (3): 325-8.

Kaufman, RH, Reeves, KO, Dougherty CM. Severe atypical endometrial changes and sequential contraceptive use. JAMA. 1976 Aug 23;236(8):923-6.

Reeves, KO et al. Exogenous estrogens and endometrial cancer. J Reprod Med. 1977 Jun;18(6):297-300.

Reeves, KO et al. Vulvar ectopic breast tissue mimicking periclitoral abscess. Am J Obstet Gynecol. 1980 Jun15;137(4):509-11.

Johnson CD and Reeves KO. Grand rounds in critical care. Alcohol and sex. Heart Lung. 1983 Jan;12(1)93-7.

Reeves KO et al. Sigmoidovaginal fistula secondary to diverticular disease. A report of three cases. J Reprod Med. 1988Mar;33(3):313-6

Weitzman GA, Kornman MO, Reeves KO et al. Endocervical brush cytology: An alternative to endocervical curettage? J Reprod Med. 1988 Aug;33(8); 677-83.

Ang MS et al. Colposcopically directed biopsy and loop excision of the transformation zone. Comparison of histologic findings. J Reprod Med.1995 Mar;40(3):167-70.

Kornman MT, Kimball, KT and Reeves, KO. Preterm external cephalic version in an outpatient environment. Am J Obstet Gynecol. 1995 Jun;172(6):1734-8.

Kaufman RH, et al. Relevance of human papillomavirus screening in management of cervical intraepithelial neoplasia. Am J Obstet Gynecol. 1997 Jan;176:87-92.

Poindexter A, et al. Comparison of spermicides on vulvar, vaginal, and cervical mucosa. Contraception. 1996 Mar;53(3):147-53.

Reeves, KO, Young, AE and Kaufman, RH. A simple, inexpensive device for teaching the loop electrosurgical excision procedure. Obstet Gynecol 1999;94:474-475.

Reeves, KO. Hormone Therapy for the Female Performing Artist. Med Problems of Performing Artists. 2005:48-51.

Hurtado, EA, Bailey HR, Reeves KO. Rectal erosion of synthetic mesh used in posterior colporrhaphy requiring surgical removal. Int. Urogynecol J. 2007:18: 1499-1501.

Toy E et al. Case Reports in Pathology. 2008. McGraw-Hill.

Chan R.C, Fletcher S., Antosh, D., Khavari R., Stewart J.,Chen J., Zurawin J., Flores J, Reeves, K. Randomized controlled trial of prophylactic ureteral stent placement during uterosacral ligament suspension. Female Pelvic Med Recon Surg 2014:Jul/Aug;(20) S18-19.

III. Teaching Information

A. Resident Training: Resident Liaison, Methodist Hospital Ob/Gyn service and Baylor Ob/Gyn resident staff. 1995-2000. Monthly thirty-minute meeting to orient residents to the service, additional administrative requirements of one hour/month.

B. Attending Staff, Baylor Cervical Dysplasia Clinic, 1978-2002 Weekly attendance at the clinic, two hours/week for 25 years. Clinic staffed with residents and medical students on the pathology/dysplasia clinic elective.

C. Attending Staff, Ben Taub General Hospital Gynecology Service. Monthly staffing for gynecology surgical cases, 1976-2005

D. Baylor Ob/Gyn Preceptor for core medical student rotations, 1976-2005. Students assigned to private service for two of the eight weeks on core rotation.

IV. Medical and Service Information

A. Patient care responsibilities
Attending Physician, Methodist Hospital Obstetrics and Gynecology Service 1976-2013

B. Administrative assignments
1. Baylor Ob/Gyn Resident Selection committee, 1995-1998

V. Community Activities

A. “Sex, God & Me” Speaker/Panel Member
1. St. Luke’s United Methodist Church, Houston, Texas, Spring 1997
2. St. Luke’s United Methodist Church, Houston, Texas, Spring,1998
3. St. Martin’s Episcopal Church, Houston, Texas, Spring, 1998
4. Holy Cross Episcopal Church, Stafford, Texas, Winter, 1999
5. Memorial Presbyterian Church, Houston, Texas October 2000
6. Chapelwood United Methodist Church, Houston, Texas January 2001
7. Holy Cross Episcopal Church, Sugar land, Texas February 2002

VI. International Activity

A. Surgical mission to Hospital Bienfaisance, Pignon, Haiti, May, 2016.

Diplomate, American Board of Obstetrics & Gynecology
Fellow, American College of Obstetricians & Gynecologists
Clinical Professor of Obstetrics and Gynecology, Weill Cornell Medical College
Emeritus Physician, Houston Methodist Hospital

4846 McDermed Drive
Houston, Texas 77035
713-898-4836
kreeves744@gmail.com

Keith O. Reeves, M.D., F.A.C.O.G.

FEE SCHEDULE EFFECTIVE 1/1/19:

Research, conferences, e-mails, report writing: $500/hr

Depositions: $500/hr

Trial testimony: $500/hr.

KEITH O. REEVES, M.D.

Previous Testimony:

1. Case No. 2:11-cv-00837; *Deborah Villnave v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
2. Case No. 2:12-cv-06600; *Alma Messer v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
3. Case No. 2:12-cv-05532; *Debra Mitchell v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
4. Case No. 2:12-cv-00173; *Krista Groover v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
5. Case No. 2:13-cv-02038; *Myra White Ross v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
6. Case No. 2:13-cv-02168; *Pamela Gruman v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
7. Case No. 2:13-cv-21072; *Shelly Shelton v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
8. Case No. 2:13-cv-32756; *Pamela Douglas Jones v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
9. Case No. 2:12-cv-01202; *Diane Kropf v. Ethicon, Inc., et al.*, In the U.S. District Court of West Virginia, Southern District;
10. Case No. 1:12-cv-00335; *Sandra Wolfe v. Ethicon, Inc., et al.*, In the U.S. District Court of West Virginia, Southern District;
11. Case No. 2:13-cv-01463; *Debra Ruberti v. Ethicon, Inc., et al.*, In the U.S. District Court of West Virginia, Southern District;
12. Case No. 2:13-cv-20202; *Ann Frady v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
13. Case No. 2:14-cv-11882; *Darlene Hartwell v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
14. Case No. 2:13-cv-10925; *Margaret Carroll v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
15. Case No. 2:13-cv-14021; *Jeanna Dayhoff v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
16. Case No. 2:13-cv-10929; *Lynn Johnson-Swan v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
17. Case No. 2:14-cv-09868; *Sara Moody v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
18. Case No. 2:15-cv-14871; *Tabitha Mueller v. C.R. Bard, Inc.*, In the U.S. District Court of West Virginia, Southern District;
19. Janet Gager v. Karl Storz
20. Rachel King v. Storz

21. Sehg v. Olympus
22. Wahrhan v. Olympus
23. Kimler v. Ethicon, Inc., et al.
24. Darlene Hartwell v. C.R.Bard
25. Eva Torres v. Ethicon (case still in discovery phase as of 9/19)